

REMARKS

The amendments to the claims do not add new matter. Claim 111 has been amended to recite that the “assembled implant is “suitable for implantation into a patient.” Support for the “assembled implant” being “suitable for implantation into a patient” is found throughout the specification, including at page 4 line 19 (“...shipment to physicians for use in implantation procedures.”). Accordingly, this amendment to claim 111 would not add new matter.

The amendment to claim 117, changes the term “graft” for which there was no antecedent support in the claim, to “implant” for which there is antecedent support in the claim. Accordingly, this amendment to claim 117 would not add new matter.

For all these reasons, the two amendments to the claims do not add new matter.

Summary of the Bases for Rejection/Objection

Claims 111-118 and 120-128 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over all claims in USSN 10/375,540.

Claim 117 is rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness.

Claims 111-118, 120-123 and 126-127 are rejected under 35 U.S.C. § 102(b) over Albee, Scientific American, “Bone Surgery with Machine Tools,” 154(4) 178-181 (1936).

Claims 111-118 and 120-128 are rejected under 35 U.S.C. § 103(a) over U.S. Pat. 5,989,289 (Coates) in view of EP 517030 (Siebels).

Claims 111-118 and 120-128 are rejected under 35 U.S.C. § 103(a) over U.S. Pat. 5,192,327 (Brantigan) in view of U.S. Pat. 5,989,289 (Coates).

The Applicants will answer each of these bases for objection in Sections I-V, respectively which follow.

I. Obviousness-type Double Patenting

Claims 111-118 and 120-128 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over all claims in co-pending sister application USSN 10/375,540. No claims have been deemed allowable in the present application or in co-pending sister application USSN 09/722,205. The Applicants will address the issue when it becomes ripe as when one or more claims become allowable in either application.

II. 35 U.S.C. § 112, Second Paragraph

Claim 117 is rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. According to the Patent Office, the term “graft,” as used in claim 117, lacks an antecedent basis. In response, the Applicants have amended claim 117, by deleting the word “graft” and substituting therefor the word “implant” for which there is an antecedent basis. Accordingly, this basis for rejection has been rendered moot.

III. 35 U.S.C. § 102(b) over Albee

Claims 111-118, 120-123 and 126-127 are rejected under 35 U.S.C. § 102(b) over Albee, Scientific American, “Bone Surgery with Machine Tools,” 154(4) 178-181 (1936). Citing to “all figures, specifically figures 10-12 and 15,” the Patent Office states that Albee discloses the elements of claim 111:

- a first cortical bone portion;
- a second cortical bone portion;
- said first cortical bone portion and said second cortical bone portion having one or more through holes sized and positioned for receiving one or more retention pins for connecting said first cortical bone portion to said second cortical bone portion; and
- one or more retention pins of appropriate diameter for connecting said first cortical bone portion to said second cortical bone portion to form said assembled bone implant as a unitary body.

[Claim 111.]

The Applicants respectfully disagree.

Albee only has Figures 1-6. However, when the Patent Office is referring to FIGS. 10-12 and 15 of Albee, it is believed that the Patent Office is referring to the subparts in Figure 3 of Albee, which has subparts 1-15 therein. If the Applicants are wrong, then the Applicants request a corrected Official Action wherein the Figures are properly designated and the Applicants are not required to speculate.

1. Albee Does Not Disclose Implants That Exist in Assembled Form Outside the Body

As an initial matter, Applicants point out that the applicants are claiming an “assembled” implant that exists in “**assembled**” form outside the body (*in vitro*) and that is “suitable for implantation in the patient’s body.” They are “off the shelf” assembled devices (i.e., devices in the mechanical sense). In marked contrast, any of the grafts disclosed in Figure 3 of Albee exist only in their disclosed form inside the body (**in vivo**). There is no “assembled” implant disclosed in Albee that exists outside the body. Rather, Albee discloses shaping a **single** piece of the patient’s own (autograft) bone to fit between two opposing segments of the patient’s living **in vivo** bone to bridge a size gap or hold the two opposing living segments in appropriate juxtaposition. The resulting assembled structure is not an “assembled implant” it is a reconstructed area. Moreover, whatever is assembled in a patient in Albee exists only *in vivo*, and is not “suitable for implantation in a patient” because it would require removing the patients’ own bones and the interconnecting piece so that they exist *in vitro* so as an assembled implant. Thus, at no time does Albee ever teach an “assembled implant” suitable for implantation in the body. Consistent with this interpretation, the Applicants have expanded the preamble of independent claim 111 to recite that the already “assembled implant” is “suitable for implantation in a patient.”

Throughout Albee’s disclosure, Albee discloses that the **single** piece of

bone is removed from one portion of the patient as **living** tissue, is shaped and then transferred as a **single** (living) piece to the living bone in the body of the patient:

The **graft lives** if it is supplied sufficiently early and in quantity with blood from the host.

[Albee at page 180, col. 1; emphasis added in bold.]

* * *

The **vascular channel**, especially the **capillaries**, in the **graft** and host bone unite.

[Albee at page 180, col. 3; emphasis added in bold.]

* * *

Compression may kill **bone cells**, either **in graft** or host tissues, or close blood vessels that should otherwise bring nourishment **to the living graft cells**.

[Albee at page 181, col.2; emphasis added in bold.]

* * *

The successful **living bone-graft** is based upon a tripod of exacting conditions and environment as to mechanics, physiology and biology.

[Albee at page 181, col.2; emphasis added in bold.]

Thus, at no time does Albee disclose an isolated “assembled implant” that is suitable for implantation in a patient. Further, drawing 7 in Figure 3 of Albee is the only drawing that discloses the use of more than one isolated piece of bone. It shows the use of two pieces of bone that would be connected in the living body sequentially and never as “an assembled implant.” For these reasons also, Albee would not be anticipatory of claim 111 or any of its dependents.

2. **Half of the Items disclosed in Figure 3 of Albee are a cabinet maker's "joinery" which Albee presents for "analogy"**

Addressing the merits of the rejection, in Figure 3 of Albee, each of subparts 1a, 2b, 3a, 4a, 5a, 6a, 7a, 7b, 8a, 9a, 10a 11a, 11b, 12a, 13a, and 15 are cabinetry joints (*i.e.*, "**joinery** elements"), which Albee cites to as analogy, and not actual implants in a patient:

The fine **joinery element** in bone surgery-a group of self evident **analogies**.

[Albee at caption to Figure 3; emphasis added in bold.]

* * *

For help with the mechanical problem, **one must go to the joiner** and **study** his various forms of **mortise** and how he selects each according to the mechanical demands of the situation (Figure 3).

[Albee at page 180, col. 2; emphasis added in bold.]

In Figure 3, only subparts 1, 2, 2a, 3, 4, 5, 6, 8, 9, 10, 11, 12, 13, and 14 show a bone repair using a **single** isolated and shaped piece of living bone to connect or bridge the gap between adjacent pieces of bone *in vivo*. As discussed above, subpart 7 of Figure 3 discloses the use of two separate pieces of bone that are connected (by the disclosed mortise and tenon joint) only when attached to the body (*in vivo*). Thus, at no time does Albee teach or suggest an "assembled implant suitable for implantation in a patient."

In the Official Action, the Patent Office specifically relies upon Figures 10-12 and 15 (*i.e.*, subparts 10-12 and 15 of Figure 3). [official Action at page 3.] However, the drawing in subpart 10, is merely a fractured femur having the ball (head) of the femur connected to the shaft by a living dowel. Again, it should be remembered that the femur so reconnected exists only *in vivo* and does not teach or suggest a stand alone assembled implant. In fact, Albee teaches against it by stating that the graft tissue **must be living**.

Regarding subparts 11 and 12 of Figure 3, the Patent office contends that "Albee teaches **superimposed** first and second cortical bone portions **each hav[ing] a D-**

shape having a through hole which receives the I shaped pin interpreted as having an appropriate **diameter**.” [Official Action at page 3: emphasis added in bold.] As an initial matter, the planar-faced dovetail of subpart 11 and the planar I-shaped connector of subpart 12 do not have “diameters.” One skilled in the art understands that by definition a “diameter” is only relevant to objects having a circular cross-section:

diameter- the straight line passing through the center of a circle, sphere, etc., from one side to the other. 2. the length of such a line; width or thickness of a circular or somewhat circular, figure or object.

[Exhibit B: Webster’s New World Dictionary, Second College Edition, Ed, Guralnik, Prentice Hall Press, Cleveland Ohio 1986 at page 389.]

Thus, on their face, subparts 11 and 12 of Figure 3 of Albee are not anticipatory. Further, the alleged “superimposed” D-shaped bone portions of subparts 11 and 12, do **not each have a “D” shape**. Each standing alone is “C”-shaped because there is no closed surface encompassing a central through hole. Moreover, because there is no closed surface, there is no “through hole.” Rather, each “C” has a slot. Further, the two allegedly “D” shaped bone portions are **not superimposed** or stacked as that phrase is used in the Applicants invention. At best, they are in a side-by-side position. However, the Patent Office has withdrawn claim 19 from consideration which is directed to a “side-by-side” embodiment. Finally, Albee teaches that subparts 11 and 12 of Figure 3 show tension members to broken knee caps:

Numbers 11 and 12 are keyed-in tension members in **broken knee caps** which will not join.

[Albee at p. 179, caption to Figure 3; emphasis added in bold.]

Because the broken knee caps are in the patient (each half being joined by opposing ligaments), only the **single** dovetail or the I piece is implanted. There is no “assembled implant” that exists outside the body that is “suitable for implantation.”

Regarding claim 116, the Patent Office contends that subpart 15 of Figure 3 is a “mirror image.” To the extent that subpart 15 is a mirror image, it is a mirror image of two pieces of joined wood. It is not an “assembled implant” composed of cortical bone portions, wherein the assembled implant is “suitable for implantation in a patient.” Further, as shown, it could not be a mirror image repair in the body because the opposing ends of the bone would be inherently different. In addition, it could not be a repair to a single bone because the bone would have to break exactly in that shape or be undesirably shortened by sawing the broken ends of the bone to achieve the overlapping shape. For this reason, subpart 15, which is directed to pieces of wood, would not be anticipatory of any of the Applicants’ claims, including claim 116.

Lastly, the patent Office contends that regarding claim 121 that “figures 11-12 are sized and shaped in the form of a cervical implant.” [Official Action at page 3.] The Applicants respectfully agree. As already discussed above, Albee expressly discloses that subparts 11 and 12 of Figure 3 are “knee caps” *in vivo* having tension members inserted. [Albee at caption to Figure 3; emphasis added in bold.] They are not assembled implants. as a practical matter, one skilled in the art recognizes that knee caps are much too large for insertion between any vertebrae and particularly cervical vertebrae. Their overall large size would cause them to either protrude from the vertebrae or sever the spinal cord of the recipient.

For all these reason, Albee would not be anticipatory of any of claims 111-118, (withdrawn claim 119), 120-123, and 126-127 of the present invention.

IV. 35 U.S.C. § 103(a), Coates over Siebels

Claims 111-118 and 120-128 are rejected under 35 U.S.C. § 103(a) over U.S. Pat. 5,989,289 (Coates) in view of EP 517030 (Siebels). According to the Patent Office, “[r]eferring to all figures, Coates teaches a D-shaped cortical bone spinal implant. . . .” [Official Action at pages 4 citing to Coates at col. 11, lines 42 et seq.] The Patent Office admits that **“Coates et al fails to teach said implant can comprise a first and**

second portion capable of being connected by a pin.” [Official Action at page 4; emphasis added in bold.] To make up for this deficiency, the Patent Office cites to Siebels, stating that Siebels discloses “a spinal implant and teaches stacking portions 11 of the implant and connecting said portions with pins 17.” [Official Action at page 4.] The Patent Office then concludes that “[i]t would have been obvious to one skilled in the art to have utilized the teachings of Siebels to stack and connect the individual implant portions with the D-shaped cortical bone implant of Coates wherein multiple portions could be stacked and connected by at least one pin in corresponding through holes to adjustably build the implant to a desired height (thickness) to best fill the disk space as desired by the surgeon.” [Official Action at page 4.] The Applicants respectfully disagree.

In order for an invention to be obvious, “Both the suggestion and the **expectation of success** must be founded in the **prior art**, not in applicant’s disclosure.” *Amgen v. Chugai*, 18 USPQ2d 1016, 1022 (Fed. Cir. 1991); emphasis added in bold. In the present case, Siebels discloses that it was an object of their invention to make an implant that can “**easily** be manufactured for a multiplicity of overall dimensions:”

Therefore, the objective to develop an implant of the kind mentioned at the outset, which can rapidly be implanted and which - from the standpoint of manufacturing engineering - can also **easily be manufactured** for a multiplicity of overall dimensions, forms the basis of the [proposed] invention.

In accordance with the invention, the set objective is achieved with the help of the features, cited in claim 1.

[English Translation of Siebels at page 2, line 20 to page 3, line 1; emphasis added in bold.]

To achieve the “ease” of manufacturing, Siebels relies upon cutting discs out of “**prefabricated solid or hollow strand.**” [English Translation of Siebels at page 3, line 7.] Specifically, Siebels discloses that this mode of manufacturing, comprising cutting appropriately sized strands made of “**fiber reinforced plastic**” provides for “manufacturing” in a “**extraordinarily easy way**”:

The disk-shaped implant is preferably made of **fiber-reinforced plastic** [FRP]. In accordance with a preferred embodiment of the invention, in order to produce a single-piece implant, the disk is **cut** out of a hollow strand, which consists of a **multiple number of braiding layers [plaiting layers]**. **The braiding layers, are wound up one after another on a correspondingly shaped mandrel [arbor], preferably on a mandrel, having rectangular cross-section and rounded corners, directly in a braiding machine. The disks are cut off with the desired height,** which can vary over the disk. Implants of this kind are characterized in that they can be **manufactured** in an **extraordinarily easy way**, in which the **fiber orientation** equally imparts an **optimal rigidity** and strength to the implant.

[English Translation of Siebels at page 3, line 22 to page 4, line 9; emphasis added in bold.]

Thus, the heart of Siebel's invention is a prefabricated template that can be cut into directly useable slices to produce an implant "in an **extraordinarily easy way**." By use of the adjective "extraordinary," Siebels meant to convey that the disclosed process of manufacturing plastic implants was not just "**easy**" but "**extraordinarily easy**."

In addition, the above quote from Siebels teaches that "fiber orientation" is important because it "imparts an **optimal rigidity**." The word "optimal" is a superlative and means "most favorable or desirable; **best**; optimum." [Exhibit B: Webster's New World Dictionary, Second College Edition, Ed. Guralnik, Prentice Hall Press, 1986 at page 999; emphasis added in bold.] Thus, fiber orientation is a necessary element in the material used by Siebels to "impart optimal rigidity."

In contrast to the "**extraordinarily easy**" method of manufacturing disclosed in Siebels (that provides for an implant having "**optimal rigidity**"), Coates discloses that "developing an implant having the biomechanical properties of metal and the biological properties of bone without the disadvantages of either has been **extremely difficult or impossible**." [Coates at col. 3, lines 35-39.] By this statement, Coates teaches that as of its filing date (October 1995), cortical bone was not a "traditional orthopedic implant material" for spinal implants. It was considered "**extremely difficult or**

impossible” to provide an implant that had the benefits of both bone and metal without their undesired properties. The words “**extremely difficult or impossible**” are superlatives related to difficulty or impossibility. Given this “**extremely difficult or impossible**” setting, one would not have been motivated to substitute the cortical bone of Coates for the preformed plastic of Siebels. Given the art recognized **extreme difficulty** or **impossibility**, one skilled in the art would have even been less motivated to build an implant from little pieces of bone held together with pins, and there would not have been a reasonable expectation of success that the Applicants’ would have been able to make implants for use in the spine from assembled pieces of cortical bone. *See Amgen v. Chugai*, 18 USPQ2d at 1022. For these reasons, claims 111-118 and 120-128 would not have been obvious under 35 U.S.C. § 103(a) over U.S. Pat. 5,192,327 (Brantigan) in view of U.S. Pat. 5,989,289 (Coates).

For this reason and all of the above reasons, the combination of Coates and Siebels would have failed to render obvious claims 111-118 and 120-128 at the time that the Applicants’ invention was made.

V. 35 U.S.C. § 103(a), Brantigan over Coates

Claims 111-118 and 120-128 are rejected under 35 U.S.C. § 103(a) over U.S. Pat. 5,192,327 (Brantigan) in view of U.S. Pat. 5,989,289 (Coates). According to the Patent Office, Figures 2 and 5 of Brantigan teach a D-shaped implant comprising:

- a first portion 21;
- a second portion 21;
- said first portion and said second portion having one or more through holes 24 sized and positioned for receiving one or more retention pins 15 for connecting said first ~~cortical-bone~~ [sic] portion to said second ~~cortical-bone~~ [sic] portion; and
- one or more retention pins of appropriate diameter for connecting said first ~~cortical-bone~~ [sic] portion to said second ~~cortical-bone~~

[sic] portion to form said assembled bone implant unitary body.

[Official Action at page 5; strikeout corrections added.]

The above statement from the Patent Office is incorrect on its face because Brantigan never discloses any component or “portion” of an implant that is made of “cortical bone.” In a later sentence in the Official Action, the Patent Office acknowledges that “Brantigan **fails to teach** that the **first and second portions are cortical bone.**” [Official Action at page 5; emphasis added in bold.] Thus, in the Patent Office’s argument, the terms “said first cortical bone portion” and “said second cortical bone portion” lack antecedent basis and the resulting argument is indefinite. As a result, it is difficult to know what the Patent Office is contending.

1. **When Brantigan is Properly interpreted, there is no Motivation to substitute the cortical bone of Coates for the “fiber reinforced plastic” in the implants of Brantigan**

The Patent Office next contends that “[i]t would have been obvious to one of ordinary skill in the art to have used cortical bone which is a traditional, orthopaedic implant material as taught by Coates for any of the elements of Brantigan because ‘5,192,327 to Brantigan teach hollow *metal* cage structures. Unfortunately, due to the stiffness of the material, some *metal* implants may stress shield the bone graft, increasing the time required for fusion or causing the bone graft to resorb inside the cage. Subsidence, or sinking of the device into bone, may also occur when metal implants are implanted between vertebrae if fusion is delayed. *Metal* devices are also foreign bodies which can never be fully incorporated into the fusion mass.’” [Official Action at page 6.] The Applicants respectfully submit that Coates misinterprets Brantigan.

Specifically, Coates **teaches away** from the use of metals, just as Brantigan **teaches away** from metals. As a matter of law, “A prior art reference may be considered to teach away when ‘a person of ordinary skill, upon reading the reference, would be **discouraged from following the path set out in the reference**, or would be led in a

direction divergent from the path taken by the applicant.” *Monarch Knitting v. Sulzer*, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998) (emphasis added in bold.). In particular, Brantigan teaches that fiber reinforced plastics are “preferred” over metals:

The implants are **preferably** made of **radiolucent** material such as **carbon fiber reinforced polymers** known commercially as "Peek", (polyetherether ketone) or "Ultrapek" (polyether ketone, ether ketone, ketone). **Alternately**, polycarbonate, polypropylene, polyethylene and polysulfone type **plastics** material filled with **glass or carbon fibers** can be used. Such materials are supplied by ICI Industries of Wilmington, Del.; Fiber-Rite Corporation of Winona, Minn. or BASF Corporation.

[Brantigan at col. 3, lines 9-18; emphasis added in bold.]

In fact, other than in Brantigan’s Abstract, Brantigan never mentions the five specific metals (that are the traditional orthopaedic materials). Thus, Brantigan taught away from the use of metals by teaching that **fiber reinforced plastic** (as also used in Siebels), is a preferred alternative to metals. Coates never addressed Brantigan’s primary disclosure, which is directed to the use of fiber reinforced plastics which is the heart of Brantigan’s invention. Further, Coates’ arguments at col. 2, lines 54-65 regarding the stress shielding caused by the stiffness of titanium alloys (114Gpa) and 316L stainless steel (193Gpa) versus cortical bone (about 17Gpa) do not apply to the carbon fiber reinforced PEEK (17.8 Gpa), carbon fiber reinforced polyetherketoneetherketoneketone (PEKEKEKK) (6.9-29.4 Gpa) or carbon fiber reinforced polycarbonate (4.1-21.4 Gpa) as disclosed in Brantigan at col. 3, lines 9-13. [See Exhibit A: from www.matweb.com at page 2, line 10 “Flexural modulus”.] These fiber reinforced polymers have a stiffness (e.g. 17.8 Gpa) that is analogous to the stiffness cortical bone (about 17 Gpa) and substantially less than the stiffness (114-193 Gpa) of the recited metals. Thus, the fiber reinforced plastics of Brantigan do not have the disadvantage of “stress shielding” that is associated with metals. Further, the fiber reinforced plastics of Brantigan (and Siebel) offer yet another advantage of cortical bone because, unlike metals, both are transparent to X-rays. (See Coates at col. 2, lines 62-65 (“Moreover, **bone** as an implant also allows excellent postoperative imaging

because it **does not cause scattering like metallic implants on CT or MRI imaging.**”); Brantigan at col. 3, lines 9-10 (“The implants are preferably made of **radiolucent material** such as **carbon fiber reinforced polymers** known commercially as ‘Peek’ (polyetheretherketone) or ‘ultrapeek’ (polyether ketone, ether ketone, ketone)”); and Siebel – Eng translation at page 6, 2nd full ¶ (“Preferably, the disks are made of a **carbon-fiber reinforced plastic (CFP)** whereby the anchoring means - according to the design of the implant - can consist of the same, or another material. The manufacturing of the entire implant of CFP has the advantage that **the implant does not bring about any scattering of rays**, so that the spinal column and the adjacent biological tissue can also be examined after the implantation of a spinal-column replacement with the help of **all image-producing methods (CT, MR)**,” emphasis added in bold). Thus, Coates misstates the teaching in Brantigan, which is not limited to metal implants, but rather is directed as its preferred embodiment to implants made from “carbon fiber reinforced plastic.” Hence, one skilled in the art, upon reading both Coates and Brantigan, would not have been motivated to substitute the cortical bone of Coates for the fiber reinforced plastic of Brantigan, which Coates never discussed.

2. There is No Suggestion to Substitute Cortical Bone for Plastic or a Reasonable Expectation of Success

The Patent Office next contends that it “would have been obvious to one having ordinary skill in the art to have utilized **cortical bone which is a traditional orthopedic implant material** as taught by Coates for any of the elements of Brantigan.” The Applicants respectfully disagree.

In order for an invention to be obvious, “Both the suggestion and the **expectation of success** must be founded in the **prior art**, not in applicant’s disclosure.” *Amgen v. Chugai*, 18 USPQ2d 1016, 1022 (Fed. Cir. 1991); emphasis added in bold. In the present case, at the time of Brantigan’s 1991 filing date, Brantigan expressly teaches that the traditional orthopedic materials for spinal implants were “**nickel, chromium, cobalt, stainless steel or titanium.**” [Brantigan at the Abstract, last two lines.] At the

time of Coates' earliest claimed filing date (October 1995), Coates teaches that "developing an implant having the biomechanical properties of metal and the biological properties of bone without the disadvantages of either has been **extremely difficult or impossible**." [Coates at col. 3, lines 35-39.] Thus, at the filing date (October 1995) of Coates, Coates teaches that cortical bone was not a "traditional orthopedic implant material" for spinal implants. It was considered "**extremely difficult or impossible**" to provide an implant that had the benefits of both bone and metal without their undesired properties. Given this "**extremely difficult or impossible**" setting, there would not have been a reasonable expectation of success that the Applicants' would have been able to make implants for use in the spine from assembled pieces of cortical bone. For these reasons, claims 111-118 and 120-128 would not have been obvious under 35 U.S.C. § 103(a) over U.S. Pat. 5,989,289 (Coates) in view of EP 517030 (Siebels)..

3. **Even if Combined, the Combination of Coates and Brantigan would not make a *prima facie* case of Obviousness**

Independent claim 111 of the Applicants' invention includes as elements the following:

said first cortical bone portion and said second cortical bone portion having one or more **through holes sized** and positioned **for receiving one or more retention pins** for connecting said first cortical bone portion to said second cortical bone portion; and

one or more **retention pins of appropriate diameter** for connecting said first cortical bone portion to said second cortical bone portion to form said assembled bone implant as a unitary body.

[Claim 111: emphasis added in bold.]

Thus, one of the elements of Applicant's claim 111 is a "**retention pin of appropriate diameter**." Independent claim 120 also recites the same term "retention pin". One skilled in the art recognizes that the ordinary meaning of the term "diameter" means that the retention

pin has a substantially circular cross section. This is also seen in the circular “through holes” 701-704 of Applicants’ FIG. 7A. In contrast, Brantigan does not teach or suggest the use of any “pins” of any “diameter.” Rather, Brantigan discloses the use of a “**rectangular connecting bar**” of FIG. 3 to interconnect a plurality of D-shaped plastic devices of FIG. 2 in stacked array as shown in FIG. 5 of Brantigan:

These grooves are provided for mounting a **rectangular connecting bar 15** shown in FIG. 3. This **bar 15** has **flat side faces 15a**, rounded side edges 15b to snugly fit the grooves 14. . . .

[Brantigan at col. 4, lines 25-28; emphasis added in bold.]

The Patent Office has acknowledged that Coates “fails to teach said implant can comprise a first and second portion capable of being connected by a pin.” [Official Action at page 4.] Thus, the combination of Coates and Brantigan fail to teach or suggest an essential element of claim 111, *i.e.*, a “retention pin” having a rounded cross section of “appropriate diameter” for the through hole. Likewise independent claim 126 also recites as an element a “retention pin.” Claims 112-118, 120-125 and 127-128, which ultimately depend from claims 111 and 126, would also incorporate the limitation to a “retention pin” by reference thereto. Accordingly, claims 111-118 and 120-128 would not have been obvious over the combination of Coates and Brantigan.

CONCLUSION

The provisional rejection of all claims of this restricted invention for double patenting over all claims of a separately restricted sister application will be address at such time as claims in one of the applications has been allowed. The rejection of claim 117 under 35 U.S.C. § 112, second paragraph, for indefiniteness has been rendered moot by amendment herein. The rejection of claims 111-118, 120-123 and 126-127 under 35 U.S.C. § 102(b) over Albee have been rebutted by evidence and arguments herein. The rejection of claims 111-118 and 120-128 under 35 U.S.C. § 103(a) over U.S. Pat. 5,989,289 (Coates) in view of EP 517030 (Siebels) have been rebutted by evidence and

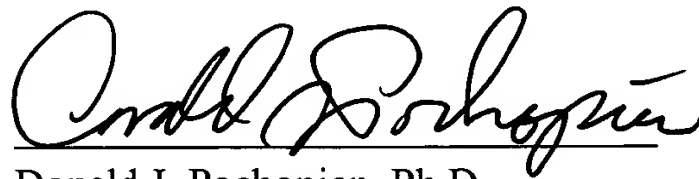
arguments herein. Finally, the rejection of claims 111-118 and 120-128 under 35 U.S.C. § 103(a) over U.S. Pat. 5,192,327 (Brantigan) in view of U.S. Pat. 5,989,289 (Coates) have been rebutted by evidence and arguments herein.

The allowance of claims 111-118 and 120-128 is respectfully requested.

Respectfully submitted,

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		SGL Carbon Group 30% SIGRAFIL C® - filled PEEK	Overview - Polyetherketoneetherketoneketone (PEKEKK), Carbon Fiber Filled	Overview - Polycarbonate, Carbon Fiber Reinforced
Physical				
1	Density (g/cc)	1.4	1.33 - 1.41	1.21 - 1.39
2	Water Absorption (%)	0.17	0.1 - 0.2	0.08 - 0.2
3	Linear Mold Shrinkage (cm/cm)	--	0.0005 - 0.001	0.0005 - 0.0053
4	Linear Mold Shrinkage, Transverse (cm/cm)	--	0.015	--
Mechanical				
5	Hardness, Rockwell R	--	--	118 - 120
6	Tensile Strength, Ultimate (MPa)	218	183 - 269	83 - 200

7	Tensile Strength, Yield (MPa)	--	--	110
8	Elongation at Break (%)	1.6	1.4 - 2.5	1.5 - 8
9	Modulus of Elasticity (GPa)	--	12.4 - 26.2	4.8 - 24.1
10	Flexural Modulus (GPa)	17.8	6.9 - 21.4	4.1 - 21.4
11	Flexural Yield Strength (MPa)	297	270 - 379	124 - 296
12	Compressive Yield Strength (MPa)	--	--	114 - 152
13	Izod Impact, Notched (J/cm)	--	1 - 1.1	0.48 - 1.87
14	Izod Impact, Notched (ISO) (kJ/m ²)	9	--	--
15	Izod Impact, Unnotched (J/cm)	--	8 - 9.1	2.94 - 9.5
16	Izod Impact, Unnotched (ISO) (kJ/m ²)	43.2	--	--
17	K (wear) Factor	--	5000	--
Electrical				
18	Electrical Resistivity (ohm-cm)	5500	100000	5 - 1e+010
19	Surface Resistance (ohm)	--	--	5 - 1e+010
Thermal				
20	CTE, linear 20°C (µm/m-°C)	--	--	13 - 31
21	Thermal Conductivity (W/m-K)	--	--	0.55 - 0.72
22	Maximum Service Temperature, Air (°C)	--	--	100 - 149
23	Deflection Temperature at 0.46 MPa (66 psi) (°C)	--	--	141 - 151
24	Deflection Temperature at 1.8 MPa (264 psi) (°C)	--	271 - 354	100 - 149

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25	Glass Temperature (°C)	--	--	150
26	Flammability, UL94	--	V-0	HB - V-0
Processing				
27	Processing Temperature (°C)	--	--	300 - 318
28	Mold Temperature (°C)	--	--	85 - 121
29	Drying Temperature (°C)	--	--	120
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**WEBSTER'S
NEW WORLD
DICTIONARY**
OF THE AMERICAN LANGUAGE

DAVID B. GURALNIK, *Editor in Chief*

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optic axis in a crystal not having the same properties in all directions with regard to light, a direction along which there is no apparent double refraction since both components of the light ray have the same velocity

optic disk same as BLIND SPOT (sense 1)

optician (äp tish'an) *n.* [Fr. *opticien*] a person who makes or deals in optical instruments, esp. one who prepares and dispenses eyeglasses

optic nerve either of the second pair of cranial nerves, which connect the retina of the eye with the brain

optics (äp'tiks) *n.pl.* [with sing. *v.*] [< OPTIC] the branch of physics dealing with the nature and properties of light and vision

optimal (äp'tə mäl) *adj.* [OPTIM(UM) + -AL] most favorable or desirable; best; optimum — **optimal-ly** *adv.*

optimism (-miz'm) *n.* [Fr. *optimisme* < L. *optimus*, best (see OPTIMUM)] 1. *Philos.* a) the doctrine held by Leibniz and others that the existing world is the best possible b) the doctrine or belief that good ultimately prevails over evil 2. the tendency to take the most hopeful or cheerful view of matters or to expect the best outcome; practice of looking on the bright side of things — **optimist** (-mist) *n.* — **optimistic** (-mis'tik), **optimistic-ally** *adv.*

optimize (-miz') *vi.* -mized', -miz'ing to be given to optimism — *vt.* to make the most of; develop or realize to the utmost extent; obtain the most efficient or optimum use of — **optimization** *n.*

optimum (-mäm) *n., pl. -mums, -ma* (-mä) [L., neut. of *optimus*, best < *ops*, power, riches: for base see OPUS] 1. the best or most favorable degree, condition, amount, etc. 2. *Biol.* the amount of heat, light, moisture, food, etc. most favorable for growth and reproduction — *adj.* most favorable or desirable; best; optimal

option (äp'shän) *n.* [Fr. < L. *optio* < *optare*, to wish, desire, ult. < IE. base **op-*, to choose, prefer] 1. the act of choosing: choice 2. the power, right, or liberty of choosing 3. something that is or can be chosen; choice 4. the right, acquired for a consideration, to buy, sell, or lease something at a fixed price, sign or renew a contract, etc. within a specified time — *vt.* *Sports* to transfer (a player) to a minor league with the option of recalling him — *SYN.* see CHOICE

optional (-'l) *adj.* left to one's option, or choice; not compulsory; elective — **optional-ly** *adv.*

optoelectronics (äp'tō i lek'trān'iks) *n.pl.* a branch of electronics involving the use of optical technology — **optoelectronic** *adj.*

optometer (äp tām'ə tər) *n.* [see OPTIC & -METER] an instrument for determining error in the refractive power of the eye

optometrist (-trist) *n.* a specialist in optometry

optometry (-trē) *n.* [see OPTIC & -METRY] 1. measurement of the range and power of vision 2. the profession of examining the eyes and measuring errors in refraction and of prescribing glasses to correct these defects — **optometric** (äp'tə met'rik), **optometric-ally** *adv.*

opulent (äp'yə lənt) *adj.* [L. *opulentus* or *opulens* < *ops*: see OPUS] 1. very wealthy or rich 2. characterized by abundance or profusion; luxurious — *SYN.* see RICH — **opulence**, **opulency** *n.* — **opulently** *adv.*

opuntia (ō pun'shē ə, -shə) *n.* [ModL. < L. (*herba*) *Opuntia*, (plant) of Opus, city in Locris, Greece] any of a large genus (*Opuntia*) of cactus plants with red, purple, or yellow flowers, pulpy or dry berries, and fleshy, jointed stems, including the prickly pears and chollas

opus (ō'pəs) *n., pl. o-pe-ra* (ō'pə rə, äp'ər ə), **opus-es** [L., a work < IE. **ops* < base **op-*, to work, riches, whence L. *ops*, riches, Sans. *āpas-*, work, OE. *efnan*, to work, do] a work; composition; esp., any of the musical works of a composer numbered in order of composition or publication

opus-cule (ō pus'kyōl) *n.* [Fr. < L. *opusculum*, dim. of *opus*: see prec.] a minor work — **opus-cular** *adj.*

opy (ō'pē) same as -OPIA

oquassa (ō kwas'ə) *n.* [< Oquassa Lake, in Maine] a small trout (*Salvelinus oquassa*) of lakes of W Maine

or (ō; unstressed ə) *conj.* [ME., in form a contr. of *other*, *auther*, either, but actually < OE. *oththe* (in *äther* . . . *oththe*, either . . . or)] a coordinating conjunction introducing an alternative; specif., a) introducing the second of two possibilities (beer or wine) b) introducing any of the possibilities in a series, but usually used only before the last (apples, (or) pears, or plums) c) introducing a synonymous word or phrase (botany, or the science of plants) d) introducing the second of two possibilities when the first is introduced by *either* or *whether* (either go or stay, whether to go or stay) e) substituted for *either* as the first correlative ('or in the heart or in the head')

or (ōr) *conj., prep.* [ME. < OE. *ār*, var. of *ær*, *ere*: cf. ERE] [Archaic or Dial.] before; ere

or (ōr) *n.* [Fr. < L. *aurum*, gold: for IE. base see EAST] *Heraldry* gold or yellow, represented in engraving by small dots powdered over a plain field

-or (ər; occas. ōr) 1. [ME. -our < OFr. -our, -or, -eur < L.

-or, -ator] a *n.-forming suffix* meaning a person or thing that [inventor, objector] 2. [ME. -our < OFr. < L. -or] a *n.-forming suffix* meaning quality or condition [horror, error]: in Brit. usage, often -our

or (ōr) *n. pl. of OS*

or-ach, or-ache (ōr'ach, är'-) *n.* [ME. *orage* < Anglo-Fr. *orache* < OFr. *arroche* < VL. **atrapica* (for L. *atriplex*) < Gr. *atraphaxys*] any of a genus (*Atriplex*) of plants of the goosefoot family, widespread in salty or alkaline areas, having usually silvery foliage and small green flowers; esp., *garden orach* (*Atriplex hortensis*), cultivated as a potherb, chiefly in France

oracle (ōr'ə k'l, är'-) *n.* [ME. < OFr. < L. *oraculum*, divine announcement, oracle < *orare*, to speak, pray, beseech < *os* (gen. *oris*), the mouth: see ORAL] 1. among the ancient Greeks and Romans, a) the place where, or medium by which, deities were consulted b) the revelation or response of a medium or priest 2. a) any person or agency believed to be in communication with a deity b) any person of great knowledge or wisdom c) opinion or statements of any such oracle 3. the holy of holies of the ancient Jewish Temple: I Kings 6:16, 19-23

oracular (ō rak'yoo lər) *adj.* 1. of, or having the nature of, an oracle 2. like an oracle; wise, prophetic, mysterious, etc. — **oracular-ly** *adv.*

oral (ōr'ad) *adv.* [< L. *os* (gen. *oris*), the mouth + -AD] toward the mouth or oral region

Oradea (ō rād'yä) city in NW Romania, near the Hungarian border: pop. 112,000

oral (ōr'əl) *adj.* [< L. *os* (gen. *oris*), the mouth < IE. base **ōus-*, mouth, edge, whence Sans. *ā-h*, mouth, ON. *ōss*, mouth of a stream] 1. uttered by the mouth; spoken 2. of speech; using speech 3. of, at, or near the mouth 4. *Phonet.* having mouth resonance only: distinguished from NASAL 5. *Psychoanalysis* a) designating or of the earliest stage of psychosexual development in which interest centers around sucking, feeding, and biting b) designating or of such traits in the adult as friendliness, generosity, and optimism or aggressiveness and pessimism, regarded as unconscious psychic residues of that stage: cf. ANAL, GENITAL 6. *Zool.* on or of the same side as the mouth — *n.* an examination that is oral and not written, as in a college — **oral-ly** *adv.*

SYN. — **oral** refers to that which is spoken, as distinguished from that which is written or otherwise communicated (an oral promise, request, etc.); **verbal**, though sometimes synonymous with **oral**, in strict discrimination refers to anything using words, either written or oral, to communicate an idea or feeling (a verbal image, caricature, etc.)

oral history 1. historical data consisting of personal recollections, usually in the form of a tape-recorded interview 2. the gathering and preservation of such data

oralism (ōr'əl iz'm) *n.* the theory or practice of teaching the deaf to read lips and to speak — **oralist** *adj., n.*

Oran (ō ran'; Fr. *ō rān'*) seaport in N Algeria, on the Mediterranean: pop. 430,000

orang (ō ran', ə-) *n.* same as ORANGUTAN

Orangé (ōr'inj, är'-) *n.* ruling family of the Netherlands: see NASSAU — *adj.* of or having to do with Orangemen

Orange (ōr'inj, är'-; also, for 3 & 4, Fr. *ō rānz'*) 1. [prob. after the orange groves there] city in SW Calif.: suburb of Los Angeles: pop. 92,000 2. river in South Africa, flowing from NE Lesotho west into the Atlantic: c. 1,300 mi. 3. former principality of W Europe, now in SE France 4. city in SE France: pop. 21,000

orange (ōr'inj, är'-) *n.* [ME. < OFr. *orenge* < Pr. *auranja* (with sp. influenced by L. *aurum*, gold & loss of initial *n* through faulty separation of art. *un*) < Sp. *naranja* < Ar. *nāranj* < Per. *nārang* < Sans. *naranga*, prob. akin to Tamil *narū*, fragrant] 1. a reddish-yellow, round, edible citrus fruit, with a sweet, juicy pulp 2. any of various evergreen trees (genus *Citrus*) of the rue family producing this fruit, having white, fragrant blossoms, often carried by brides, and hard, yellow wood 3. any of several plants or fruits resembling the orange 4. reddish yellow — *adj.* 1. reddish-yellow 2. made with or from orange 3. having a flavor like that of oranges — **orang-y** (-in jē) *adj.*

orange-ade (-äd') *n.* [Fr.: see ORANGE & -ADE] a drink made of orange juice and water, usually sweetened

Orange Free State province of South Africa, west of Lesotho: formerly a Boer republic (1854-1900) & then a Brit. colony (Orange River Colony, 1900-10): 49,866 sq. mi.; pop. 1,387,000; cap. Bloemfontein

orange hawkweed same as DEVIL'S PAINTBRUSH

Orangeism (ōr'inj iz'm, är'-) *n.* the principles and practices of the Orangemen

Orange-man (-män) *n., pl. -men* (-män) [after the Prince of Orange, later WILLIAM III] a member of a secret Protestant society organized in N Ireland (1795)

orange pekoe a black tea of Ceylon and India: see PEKOE

orange-ry (ōr'inj rē, är'-) *n., pl. -ries* [Fr. *orangerie* < *oranger*, orange tree < *orange*] a hothouse or other sheltered place for growing orange trees in cooler climates

orange stick a pointed stick, orig. of orangewood, used in manicuring

fat, äpe, cär; ten, ēven; is, bite; gō, hōrn, tōōl, look; oil, out; up, fur; get; joy; yet; chin; she; thin, then; zh, leisure; ŋ, ring; ə for a in ago, e in agent, i in sanity, o in comply, u in focus; ' as in able (ä'b'l); Fr. bäl; ä, Fr. coeur; ö, Fr. feu; Fr. mon; ô, Fr. coq; ü, Fr. duc; r, Fr. cri; H, G. ich; kh, G. doch. See inside front cover. ☆ Americanism; † foreign; * hypothetical; < derived from

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